

**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION**

In the Matter of	)	
	)	
	)	
Schering-Plough Corporation,	)	
a corporation,	)	
	)	
Upsher-Smith Laboratories,	)	Docket No. 9297
a corporation,	)	
	)	
and	)	
	)	
American Home Products Corporation,	)	
a corporation.	)	
	)	

**ORDER DENYING MOTIONS TO AMEND THE PROTECTIVE ORDER**

**I.**

On May 18, 2001, Complaint Counsel filed a motion to amend the Protective Order Governing Discovery Material, entered in this matter on May 10, 2001 ("Protective Order"). Complaint Counsel seeks to have Paragraph 5 of the Terms and Conditions of the Protective Order amended to remove Mark Robbins as an individual designated to review confidential information on behalf of Respondent Upsher-Smith Laboratories, Inc. ("Upsher-Smith"). On May 29, 2001, Upsher-Smith filed an opposition to Complaint Counsel's motion.

On May 29, 2001, non-party KV Pharmaceutical Company ("KV") filed a motion to amend the Protective Order. KV also seeks to have Paragraph 5 of the Protective Order modified so that Robbins may not examine KV's most sensitive information. On June 5, 2001, Upsher-Smith filed an opposition to KV's motion. On June 8, 2001, KV filed a reply brief in support of its motion.

By Order dated June 8, 2001, Complaint Counsel and Upsher-Smith were allowed to file reply briefs and any additional evidence indicating whether or not Robbins' duties and responsibilities involve Robbins' advice and participation in any or all of Upsher-Smith's decisions made in light of similar or corresponding information about a competitor. Those briefs have now been filed, on June 13, 2001, and June 18, 2001, respectively.

Based on the evidence presented, Complaint Counsel's and KV's motions are DENIED.

## II.

Paragraph 5 of the Protective Order provides that each respondent may designate no more than two in-house counsel “who do not have day to day business responsibilities” to see materials designated as confidential. Upsher-Smith listed only one attorney, Mark Robbins, Director of Scientific Affairs, as its designated individual. Complaint Counsel and KV argue that Robbins should not be allowed to review confidential materials on the grounds that Robbins is involved in competitive decision making. Upsher-Smith asserts that Robbins is not involved in competitive decision making.

A request to provide in-house counsel with a competitor’s confidential information “might properly be denied in a case ‘where in-house counsel are involved in competitive decision making,’ a term . . . defined as shorthand for a counsel’s activities, association, and relationship with a client that are such as to involve counsel’s advice and participation in any or all of the client’s decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor.” *Matsushita Elec. Indus. Co., Ltd. v. Int’l Trade Comm’n*, 929 F.2d 1577, 1579 (Fed. Cir. 1991) (quoting *United States Steel Corp. v. Int’l Trade Comm’n*, 730 F.2d 1465, 1468 (Fed. Cir. 1984)). “Access to confidential information may not be denied solely because of an attorney’s status as in-house counsel. . . . Rather, the decision turns largely on the specific role of in-house counsel within the business: whether he or she has a part in the type of competitive decision-making that would involve the potential use of the confidential information.” *Sullivan Marketing, Inc. v. Valassiscommunications, Inc.*, 1994 U.S. Dist. LEXIS 5824 (S.D.N.Y. 1994) (citing *United States Steel Corp.*, 730 F.2d at 1468-69; other citations omitted).

Complaint Counsel asserts that Robbins has day to day business responsibilities as he makes competitive decisions on product design and development. Complaint Counsel presents excerpts from deposition testimony of Robbins to assert that Robbins is involved in competitive decision making. In his deposition taken on May 24, 2000, Robbins testified that in his current position, Vice President, Scientific Affairs, he is responsible for clinical affairs, regulatory affairs, and quality assurance. His responsibilities include: the design and conduct of clinical trials, development of regulatory strategy and FDA interactions from drug approvals, and development of quality programs and product release. Deposition of Mark S. Robbins at 13. Complaint Counsel further presents documents, produced by Upsher-Smith, that show that Robbins attended meetings specific to certain pharmaceuticals. Complaint Counsel argues that at these meetings, competitive decisions are made with respect to product development, business negotiations, and deals with other companies. Complaint Counsel also asserts that discussions of potential legal issues such as patent infringement are held at the meetings attended by Robbins.

KV argues, generally, that a head of Scientific Affairs in the pharmaceutical industry is responsible for evaluating the likelihood of success of potential development projects, oversees research and development efforts, develops methods for clinical testing of products, and is responsible for obtaining regulatory approvals from the FDA. KV asserts that a rival Scientific Affairs Department could gain an unfair advantage from dissemination of a third parties’ highly confidential information.

Upsher-Smith asserts that Robbins is the company's only in-house counsel. The company further asserts that Robbins' authority and responsibilities over new product development and management of the research and development group, quality services laboratory, project management, clinical affairs, quality assurance and regulatory affairs are only to the extent of assuring compliance with relevant rules and regulations and that these activities are consistent with the traditional role of in-house counsel.

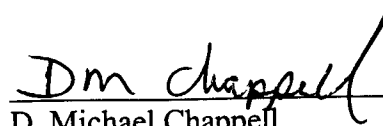
In his declaration in response to Complaint Counsel's motion, Robbins states that he provides legal advice to the company on the procedures for filing drug applications and for securing product approvals from the FDA and DEA; advises Upsher-Smith on the legal aspects of safety and efficiency issues that arise during clinical trials; and advises Upsher-Smith to ensure that its products are being developed and maintained safely and in accordance with federal regulations. Declaration of Mark S. Robbins, May 29, 2001 at ¶¶ 5, 10, 12. Robbins further declares that he does not have any responsibility for designing new products, developing marketing strategy, analyzing competitive conditions, establishing launch dates, setting prices, or other activities that could fairly be characterized as competitive decision making. *Id.* at ¶ 20.

In his supplemental declaration in response to Complaint Counsel's and KV's reply briefs, Robbins states that he does not have any role in research and development, marketing strategy, pricing or any other area where a competitor's confidential information would be potentially valuable. Supplemental Declaration of Mark S. Robbins, June 18, 2001 (Robbins Supplemental Declaration") at ¶ 2. Robbins further declares that he is not consulted with and has no participation regarding competitive issues such as which products to develop, which products to market, when to market them, and which competitors already are or may later be in the market. *Id.* at ¶ 3. Robbins states that his only role in clinical trials is in assuring that they are conducted and submitted in accordance with FDA rules and regulations. *Id.* at ¶ 4. Robbins expressly denies having any role, direct, indirect, or otherwise, in research and development. *Id.* at ¶ 8.

### III.

Complaint Counsel and KV have raised valid concerns regarding Robbins' access to confidential information. However, Robbins, through his declarations, has established that he does not participate in the type of competitive decision making that would involve counsel's advice and participation in any or all of Upsher-Smith's decisions made in light of similar or corresponding information about a competitor. Accordingly, Complaint Counsel's and KV's motions to amend the Protective Order are DENIED.

ORDERED:

  
D. Michael Chappell  
Administrative Law Judge

Date: June 20, 2001